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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/776,414	02/11/2004	Jonathan Fanger	101896-0239	2408
21125	7590	02/13/2006		
NUTTER MCCLENNEN & FISH LLP WORLD TRADE CENTER WEST 155 SEAPORT BOULEVARD BOSTON, MA 02210-2604			EXAMINER AMARELD JR, ROBERT W	
			ART UNIT	PAPER NUMBER
			3738	

DATE MAILED: 02/13/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/776,414	Applicant(s) FANGER ET AL.	
	Examiner Robert W. Amareld, Jr.	Art Unit 3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 22 December 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-73 is/are pending in the application.
4a) Of the above claim(s) 25-31, 33, 41, 42 and 44-73 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) 1-23, 32, 34-40, 43 is/are rejected.
- 7) ☒ Claim(s) 24 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 11 February 2004 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>1/17/06, 5/7/04, 6/30/04, 9/17/04, 10/8/04</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Applicant's election of claims 1-24, 32, 34-40, 43 in the reply filed on 12/22/05 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 25-31, 33, 41-42, 44-73 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention and species, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 12/22/05.

Drawings

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the "at least one tab comprising first and second tabs" of claim 5 must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the

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remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

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Claims 1, 2, 5-18, 32, 34-36 & 38-40 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-17, 25, 27 & 28-32 of copending Application No. 10664575. Although the conflicting claims are not identical, they are not patentably distinct from each other because the structure claimed is essentially identical with minor substitutions of terminology such a bore for pathway and the minor preamble difference of intended use as being for a "spinal fixation element" in the current application or as a for use with a "spinal plate" in the copending application, the applicant is respectfully reminded that intended use, as set forth in the claims, carries no weight in the absence of any distinguishing structure.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 6 & 7 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 6 recites the limitation "first and second opposed tabs". There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35

U.S.C. 102 that form the basis for the rejections under this section made in this

Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, 9-12, 13, 17-19, 21, 22, 32, 35 are rejected under 35

U.S.C. 102(b) as being anticipated by Griffin (US Pat# 24660223). Griffin discloses a guide device (Figure 1) with an elongate shaft (1) and a rectangular guide member (3) coupled to the distal end and having first and second pathways (9 & 10) in a fixed relationship to one another, extending in a proximal distal direction, and at least one alignment element (4) that is fully capable of interacting with a spinal fixation element where the bores are aligned. The at least one alignment member comprises an alignment tab (4) extending distally from the distal surface of the guide member and is fully capable of being disposed within a corresponding slot on a spinal fixation element. The guide member includes superior (top) and inferior (bottom) and opposed transverse sides (edges) where the edges have a width less than the top and bottom. The guide member being flat, flat being a shape capable of conforming to a flat spinal fixation element. The first and second pathways are at an angle to each other, that angle being zero and are defined by opposed semi-cylindrical sidewalls, opposed semi-cylindrical sidewalls being inherent in any circular bore. The at least one alignment element is adapted to prevent rotation between the guide

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member and a spinal fixation element when it consists of two alignment members being the pin (4) and the smaller pin (16), where the smaller pin comprises an ovular shape that extends distally from the guide member (Figure 4), however when one pin is in use (3) the body maintains a loose fit and is capable of pivoting where the tab may provide a sliding interference fit into a hole of an appropriately configured spinal fixation element. The cut out portion formed in the guide member would be the beveled surface at the top of each bore (11, 12), the cut out portion being in the superior wall of the top of the body (3), which may be considered a side wall if the device is held in an upright orientation. Please note the intended use, as set forth in the claims, carries no weight in the absence of any distinguishing structure.

Claims 35-38 are rejected under 35 U.S.C. 102(b) as being anticipated by Kurland (US Pat# 4686972). Kurland discloses a guide device (Figure 1) with at least one through bore pathway (21), an elongate shaft (11) and the parallel alignment tabs (14) that are capable of providing a sliding interference fit by using the non serrated flat front portion of the tab and are capable of interacting with a graft window on an appropriately configured spinal fixation element. Please note the intended use, as set forth in the claims, carries no weight in the absence of any distinguishing structure.

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Claims 1-4, 7, 8, 12, 13, 16, 21-23 34-38 & 40 are rejected under 35 U.S.C. 102(b) as being anticipated by Oxland (US Pat# 5676666). Oxland discloses a guide device which may be locked via the locking mechanism (93), the disclosure as discussed below is referring to the device in this locked stationary manner. Oxland discloses an elongate shaft comprised of the blades (68, 70) that has the proximal portion or the shaft is at an angle relative to the distal portion and has the guide member (Figure 1a) at the distal end and has tabs (76 & 78) as alignment elements where the alignment elements is fully capable of resting against the edge of and provide a sliding interference fit with an appropriately shape and constructed spinal fixation plate. The alignment tabs are positioned opposite one another where the pathways are between the tabs. The device includes rounded tips (Figures 4 & 5) that are shown disposed within the bore on a spinal fixation element, while the tabs interact with the edge of the plate. The guide device is substantially rectangular elongate (Figure 1 & 1a) and includes opposed superior and inferior and transverse sides where the transverse sides have a lesser width where the alignment tabs extend distally from the transverse opposed sides and the tabs are substantially parallel and fully capable of interacting with a graft window of an appropriately formed spinal fixation element. The device contains a cut out portion as shown in the cross section of Figure 1a, formed in one of the superior or inferior walls where the cut out portion is substantially between the first and second pathways. It is noted that the plate is disclosed as being "clipped into" the plate disclosed by Oxland, as shown in Figures 4 and 5, however the examiner maintains that an appropriately

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shaped fixation element (plate) would not require this motion to perform the functions disclosed in the current application and further more, the intended use, as set forth in the claims, carries no weight in the absence of any distinguishing structure.

Claims 1-4, 7-23, 32, 34-38, 40, 43 are rejected under 35 U.S.C. 102(b) as being anticipated by Ray III (US PG PUB # 2002/0022847). Ray discloses a substantially rectangular guide device (700, 700'), an elongate shaft, being the actuator (772) in actuator housing (770'), the actuator having a handle (774) at different angle than the distal portion of the shaft, the actuator having a flange (776) to connect with the guide member (700, 700'). The guide member having a variety of possible alignment members (Figures 33, 34, 38) where the alignment tabs (714, 715) are distal from the guide member, ovular in shape and are fully capable of providing a sliding interference fit, or sliding along the edge of, or interacting with a graft window of, or being disposed in a slot of an appropriately shaped spinal fixation element or plate where the guide member may pivot with respect to an appropriately shaped spinal fixation element. The alignment members comprises opposing tabs (714, 715) such that the pathways (761, 762) are between the tabs where the tab (76) is capable of being disposed within a bore of a spinal fixation element (SFE) where the combination of tabs may prevent rotation of an SFE, additional alignment tabs (720a,b and 722a,b) extend from the superior and inferior sides of the guide device. The pathways, defined by paths 761 & 762, or 708 & 710, extend in a proximal distal direction and are at

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a fixed angle to one another, the angle being zero and are defined by opposed semi-cylindrical sidewalls, opposed semi-cylindrical sidewalls being inherent in any circular bore where the pathways are in full communication with each other in the embodiment of the guide member (700') as shown in Figure 38. Each portion of the guide member that is absent between each tab is a cut out portion of the guide member and demonstrates a cut out portion in each face of the guide member (Figure 33) and contains a portion located between the pathways as shown under the front surface (721). The guide device having superior, inferior and opposed transverse sides where the transverse side has a lesser width. The guide device has distal surface (721) which is fully capable of conforming to the shape of an appropriately shaped SFE. The embodiments of Figures 33-39, 45-46 of Ray have mainly been relied on here, however, this does not exclude other embodiments from the prior art. Please note the intended use, as set forth in the claims, carries no weight in the absence of any distinguishing structure, the applicant is reminded that any use regarding an unclaimed spinal fixation element or plate (sliding interference fit, pivoting, etc) carries no weight as the claimed structure is capable of all of functionalities with a spinal fixation element that is appropriately constructed to allow these functions with the claimed structure.

Claims 1, 2, 6, 35, 36 & 39 rejected under 35 U.S.C. 102(b) as being anticipated by Jackowski (US Pat # 6565571, WO00/22999). The full assembly as shown in Figures 6-8 is considered here. Jackowski discloses an elongate

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shaft (33) and a guide member (36, 38, I) with at least one tab (38) and first and second pathways (19) where the tabs (38) are between the pathways. While the assembly of the implant and implant positioner itself is not disclosed for use as a guide member when assembled as such, it is fully capable of performing the intended function, even though intended use carries no weight in the absence of relevant structure

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 1, 2, 6, 35, 36 & 39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Griffin (US Pat# 2466023) in view of Jackowski (US Pat # 6565571, WO00/22999). Griffin is discussed supra. However Griffin does not disclose first and second alignment tabs placed substantially between the first and second pathways. Jackowski teaches first and second alignment tabs (38) in the same field of endeavor or the analogous art of drilling or screw guides for the purpose of alignment of a drill or screw with a specific area. It would have been obvious to one having ordinary skill in the art at the time the invention was made to combine the teaching of central alignment tabs, as taught by Jackowski, to the

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drill guide as per Griffin, in order to allow the drill guide to fully align with an element to be attached to a surface .

Claims 1, 2 & 5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Oxland (US Pat# 5676666) in view of Torode (US Pat# 6511484). Oxland is discussed supra. However Oxland does not disclose movable tabs. Torode teaches the movable tab (734) in the same field of endeavor or the analogous art of surgery for the purpose of aligning a fixation element. It would have been obvious to one having ordinary skill in the art at the time the invention was made to combine the teaching of movable tabs, as taught by Torode, to the guide as per Oxland, in order to engage the edges of a spinal fixation plate.

Allowable Subject Matter

Claim 24 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Resch, US Pat# 6673115- an implanting tool; Bray, US Pat# 6235034 – bone plate guide; Sand, US Pat# 6113602- guide.

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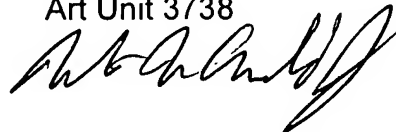
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert W. Amareld, Jr. whose telephone number is 571-272-6170. The examiner can normally be reached on M-F 9am - 5pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine M. McDermott can be reached on 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

RWA

Robert W Amareld, Jr.
Examiner
Art Unit 3738



BRIAN E. PELLEGRINO
PRIMARY EXAMINER

